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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/910,226	07/20/2001	H. James Harmon	88142/01-423	3218

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EXAMINER

LAM, ANN Y

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/910,226	Applicant(s) HARMON, H. JAMES	
	Examiner Ann Y. Lam	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 8 is/are rejected.
- 7) ☒ Claim(s) 3 and 7 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed September 17, 2001 and August 26, 2002 fails to comply with 37 CFR 1.98(a)(1), which requires a list of all patents, publications, or other information submitted for consideration by the Office. It has been placed in the application file, but the information referred to therein has not been considered.

Claim Objections

Claim 8 is objected to because of the following informalities: Claim 8, line 1, should include the word ~~of~~ after "steps". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 and 7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 recites the that two spectral values are measured. It is unclear as to the relationship of claim 6 to claim 1. That is, it is unclear as to how the two spectral values measured are being used in the invention.

Claim 7 is indefinite because it depends on claim 6, which is indefinite for the reasons set forth above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 2 are rejected under 35 U.S.C. 102(e) as being anticipated by
Schlabach et al., 4,895,809.

Schlabach discloses a method of real-time testing for the presence of an analyte in an environment, comprising the steps of:

- (a) obtaining a colorimetric indicator (i.e., fluorescently labeled antigen, column 4, lines 19-20) that has been reversibly incorporated into a binding protein (i.e., antibody, column 4, lines 19-21), said binding protein having an active site at which the analyte will bind if present (column 4, lines 18-21), said colorimetric indicator being reversibly bound at said active site to form a complex (column 4, line 20);
- (b) exposing said complex to said environment (i.e., sample, column 4, line 19);
- (c) measuring at least one spectral value of said colorimetric indicator (column 4, lines 21-22, and column 4, lines 19-22); and,

(d) determining from any spectral value so measured whether said colorimetric indicator has been displaced from said binding protein (column 4, lines 19-22) and, thus, whether or not said analyte is present within said environment (column 7, lines 22-27.)

As to claim 2, Schlabach teaches the step of immobilizing the complex on a surface (column 4, lines 16-16 and line 20-21.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schlabach et al., 4,895,809, in view of Xu et al., 5,366,866.

Schlabach discloses the invention substantially as claimed (see above). Schlabach teaches that the antibodies are immobilized on glass or polymeric beads (column 4, lines 26-29). However, Schlabach does not teach the step of immobilizing the complex on specifically a microscope slide.

Xu teaches that in immunoassays, the antibody is generally immobilized on a support, such as a bead, plate or slide (column 5, lines 50-51) and contacted with a fluorescent label (column 5, line 59.) After contacting with the sample, the liquid phase

is separated from the support (column 5, lines 53-54.) It would have been obvious to use a slide as taught by Xu to immobilize the antibody-fluorescent label complex in the assay of Schlabach because Xu shows that slides are conventional solid supports used to immobilize immunoreagents in solid phase assays, such as the assay of Schlabach.

Claims 6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schlabach et al., 4,895,809, in view of Baylor et al., 5,457,313.

Schlabach discloses the invention substantially as claimed (see above), except for two spectral values being measured (claim 6), or for the step of obtaining at least one pre-exposure spectral measurement of said colorimetric indicator and said binding protein before exposure to the sample, (d) calculating at least one numerical difference between said at least one measured spectral values and said at least one pre-exposure spectral measurements (claim 8.)

Like Schlabach, Baylor also discloses a method of determining whether an analyte, for example uranyl, is present in a sample (column 6, lines 27-29), wherein the analyte is detected through well-known absorption analysis techniques using a spectrophotometer (column 3, lines 47-49 and 65-67.)

Baylor also teaches the step of obtaining at least one pre-exposure spectral measurement of said colorimetric indicator and said binding protein before exposure to the sample (column 6, line 6), (d) calculating at least one numerical difference between said at least one measured spectral values (i.e., the spectral after exposure, column 6, line 6) and said at least one pre-exposure spectral measurements (column 6, lines 24-

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29; and column 3, lines 47-50.) The change in absorbance is attributable to the analyte (i.e., uranyl) present in the sample (column 6, lines 27-29, and column 3, lines 65-67.)

It would have been obvious to one of ordinary skill in the art to obtain a spectral measurement before and after exposure of sample to assay reagents, as taught by Baylor, in the assay method of Schlabach because such a step provides the advantage of elimination of background interference, where background interference from the initial spectral measurement is subtracted from the assay measurement to provide a more accurate analyte determination.

Allowable Subject Matter

Claims 3, 4 and 7 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the above rejected claims have been considered but are moot in view of the new ground(s) of rejection.

Examiner would like to note that this action is made final because the amendments substantially changes the scope of the claims and the previous rejection under Iwasa are appropriate as to the original claims. For example, Applicant argues on page 9 that it is incorrect to say that the Iwasa enzyme is reversibly incorporated

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into the active site of the binding protein. However, the original claims do not recite that the enzyme is incorporated into the active site of the binding protein. Applicant also argues at the bottom of page 9 and on page 11 that the spectral changes measured by Iwasa are due to the formation of a colored/fluorescent product, as opposed to a spectral change in the colorimetric indicator. However, the original claims do not recite that the spectral change is due to the colorimetric indicator itself. Applicant also argues on page 10 that AchE is used as a labeling enzyme in Iwasa. Even so, however, the original claims do not distinguish over Iwasa. Applicant also argues on page 10 that the pellets are placed on a microscope slide, not bound to it. However, the pellets are considered immobilized on a slide, as claimed.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Morozov et al., 6,033,913, discloses that all compounds binding acetylcholine esterase with high affinity may be suspected as possible poisons (column 27, lines 60-62.) Sessler et al., 5,599,923, discloses that porphyrins, such as tetraphenylporphyrin sulfonate, can serve as contrasting agents in magnetic resonance imaging (column 1, lines 53 and 66.)

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is 571-272-0822. The examiner can normally be reached on M-Sat 11-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

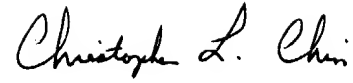
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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A.L.

A handwritten signature in black ink, appearing to be 'A.L.' with a stylized flourish.A handwritten signature in black ink, reading 'Christopher L. Chin'.

CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~ /641